

Docket No.: 231893US0 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

EXAMINER: S. GOLLAMUDI Christine NOEL, et al.

SERIAL NO.: 10/685,505

GROUP ART UNIT: 1616 FILED: OCTOBER 16, 2003

FOR: COMPOSITION IN THE FORM OF AN

OIL-IN-WATER EMULSION AND USES

**THEREOF** 

## DECLARATION UNDER 37 C.F.R. 1.132

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR:

- I, Ann-France RATEL (formerly Anne-France LIVERNETTE), hereby declare:
- 1. I am a named inventor on the above-identified patent application, and am employed by L'ORÉAL as a chemist. I have experience in the field of preparing and analyzing cosmetic and/or dermatological compositions, particularly emulsions.
- 2. The following observations and experiments were carried out by me or under my direct supervision and control.
  - 3. The following six compositions were prepared:

ing six compositions		Comparative
Invention	Comparative	Comparative
composition 1B	Example 1	Example 1A
20/	2%	2%
2%0		
	Invention	Invention Comparative composition 1B Example 1

	1000/	Qs 100%	Qs 100%
Demineralized water	Qs 100%	Q3 10074	
Cyclopentasiloxane	6%	6%	6%
	5%	5%	5%
KSG 16 (containing	370		
24% active material)			
Undecylenolyglycine	0.125%		
Glycine			0.125%
Grycine			

Ingredient	Invention	Comparative	Comparative
ingredient	composition 2B	Example 2	Example 2A
Hostacerin AMPS	2%	2%	2%
(sold by Hoescht)			
Demineralized water	Qs 100%	Qs 100%	Qs 100%
Cyclopentasiloxane	6%	6%	6%
KSG 16 (containing	15%	15%	15%
24% active material)			
Undecylenolyglycine	0.125%		0.1259/
Glycine			0.125%

- 4. Invention Composition 1B was identical to Comparative Example 1 except that Comparative Example 1 did not contain a lipophilic amino acid. Invention Composition 1B was also identical to Comparative Composition 1A except that Comparative Composition 1A contained a non-lipophilic amino acid (glycine) instead of a lipophilic amino acid.
- 5. Similarly, Invention Composition 2B was identical to Comparative Example 2 except that Comparative Example 2 did not contain a lipophilic amino acid. Invention

Composition 2B was also identical to Comparative Composition 2A except that Comparative Composition 2A contained a non-lipophilic amino acid (glycine) instead of a lipophilic amino acid.

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- 6. Comparative Compositions 1 and 2 which did not contain any amino acid, lipophilic or non-lipophilic, were unstable compositions. That is, these two compositions were unstable dispersions having large oily globules throughout. Such large oily globules are characteristic of unstable compositions.
- 7. Comparative Compositions 1A and 2A which contained a non-lipophilic amino acid were also unstable compositions. That is, these two compositions were also unstable dispersions having large oily globules throughout. Thus, both compositions having no amino acid (comparative compositions 1 and 2) and compositions containing a non-lipophilic amino acid (comparative compositions 1A and 2A) were unstable, meaning among other things that these compositions were unacceptable for commercial use.
  - 8. In stark contrast, Invention Composition 1B and 2B were stable, cream compositions. They were fine dispersions and did not contain large oily globules.
  - 9. Given the similarity of Compositions 1, 1A and 1B, and Compositions 2, 2A and 2B, it was surprising and unexpected that compositions containing a lipophilic amino acid were stable, whereas identical compositions lacking a lipophilic amino acid were not stable.
  - 10. Such surprising and unexpected results are fully representative of the present invention. That is, I would expect compositions in the form of an oil-in-water emulsion comprising an oily phase dispersed in an aqueous phase and a hydrophilic polymer, said composition further comprising:
    - (1) at least one elastomeric organopolysiloxane, and

(2) at least one lipophilic compound selected from the group consisting of lipophilic amino acid compounds, salts thereof, lipophilic salicylic acid compounds of formula (I) below, and salts thereof:

in which:

-  $R_1$  represents a hydroxyl radical or an ester of formula:

-O-CO-R4

in which  $R_4$  is a saturated or unsaturated aliphatic radical containing from 1 to 26 carbon atoms, an amine or thiol function optionally substituted with an alkyl radical containing from 1 to 18 carbon atoms,

-  $R_2$  and  $R_3$ , independently of each other, are in position 3, 4, 5 or 6 on the benzene ring and represent, independently of each other, a hydrogen atom or a radical:

$$-(O)_n$$
- $(CO)_m$ - $R_5$ 

in which n and m, independently of each other, are each an integer equal to 0 or 1; provided that R<sub>2</sub> and R<sub>3</sub> are not simultaneously hydrogen atoms;

-  $R_5$  represents a hydrogen, a linear, branched or cyclized saturated aliphatic radical containing from 1 to 18 carbon atoms, an unsaturated radical containing from 3 to 18 carbon atoms, bearing one to nine conjugated or non-conjugated double bonds, the radicals optionally being substituted with at least one substituent chosen from halogen atoms, trifluoromethyl radicals, hydroxyl in free form or esterified with an acid containing from 1 to 6 carbon atoms, or carboxyl in free form or esterified with a lower alcohol containing from 1 to 6 carbon atoms, or an aromatic radical containing from 6 to 10 carbon atoms, to possess improved stability properties like those of Invention Compositions 1B and 2B. I have no reason to expect otherwise.

- 11. The fact that the compositions of the present invention are more stable is commercially significant. More stable products are more desirable to consumers and, thus, more commercially viable. Also, active ingredients in more stable products are more likely to maintain activity longer than in unstable products, making such stable products more desirable to consumers.
  - 12. The undersigned petitioner declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believe to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.
    - 13. Further deponent sayeth not.

PATEL Anne France
Name

Robeled
Signature

Date